Cold Chain Equipment Optimisation Platform

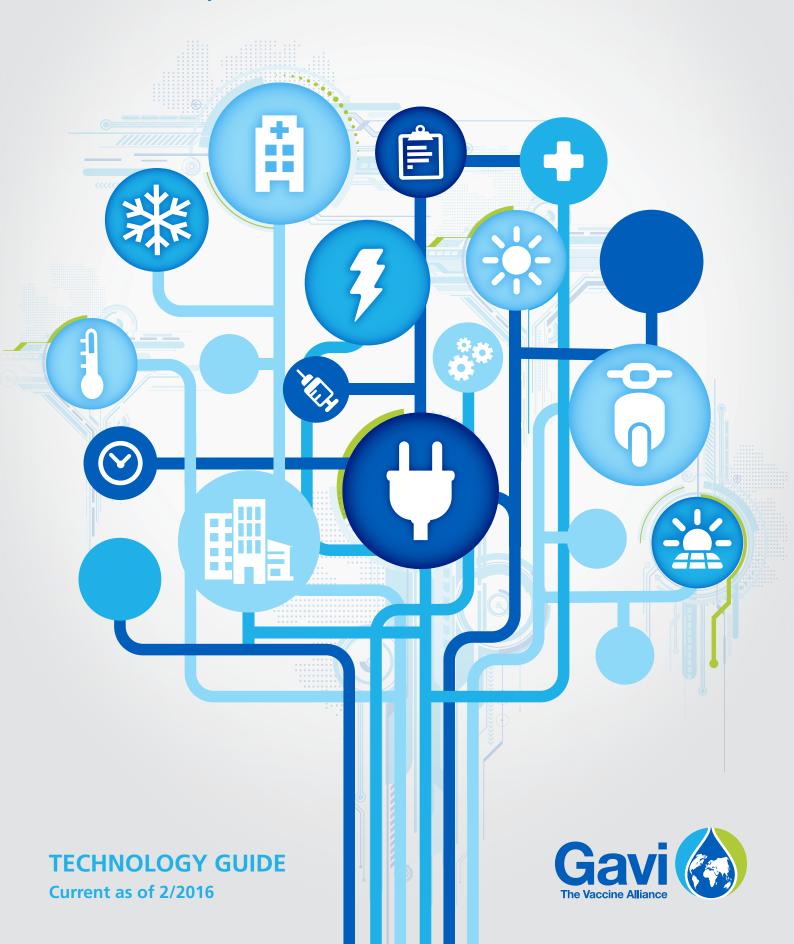


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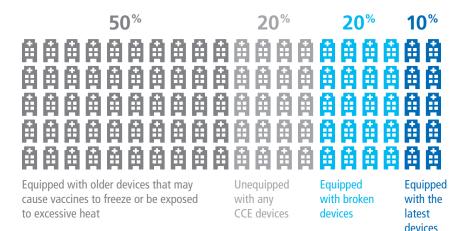
This guide is current as of Feb 2016. As information will be updated periodically, please reference http://www.gavi.org/support/apply/ to check for new information.

INTRODUCTION

Strong and efficient supply chains – equipped with reliable cold chain equipment (CCE) – are vital to helping countries increase immunisation coverage and equity, reaching children with lifesaving vaccines and protecting them against deadly diseases. To ensure that vaccines are widely available and remain cold, safe and effective throughout the entire supply chain, each country's immunisation programme needs access to high-performing and well-maintained cold chain equipment. Such cold chain equipment, when available at the required cold chain points-in-country, will increase vaccine availability, potency, and safety. This will help to improve immunisation coverage.

The challenge:

In a number of countries, as many as 90% of medical facilities are not equipped with the latest technology.



To support countries in improving their cold chains, Gavi, the Vaccine Alliance recently established the Cold Chain Equipment Optimisation Platform. Through the Platform, Gavi has committed an initial US\$50 million to jointly invest with countries to purchase and install equipment that meets specific technology requirements. By investing in new cold chain equipment, countries can ultimately save money. Some older technologies have high operating costs and/or poor temperature control that can lead to vaccine wastage if vaccines are exposed to very high or freezing temperatures.

Investing in new cold chain equipment is key to improving:



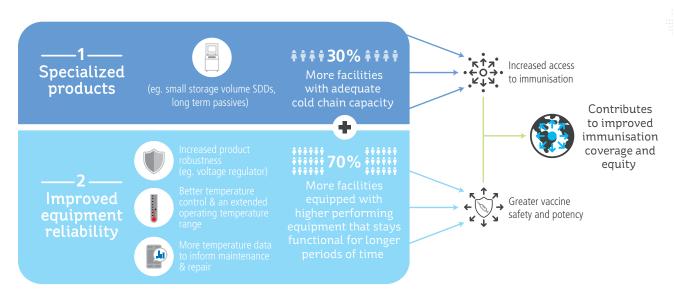
Sustainable, equitable, immunisation coverage (by extending equipment availability into remote areas and better enabling outreach activities);



Reliability and the amount of time a device can be operated; and



Vaccine safety and effectiveness through better temperature control.



As you begin thinking about the equipment currently in use in health facilities in your country, imagine the following possibilities:

- Fridges that are able to keep vaccines cool and safe even if the power is out for multiple days;
- Remote facilities that keep vaccines cool using dependable solar-powered devices that do not need batteries;
- New device design features that make accidental freezing of vaccines very unlikely and contribute to reductions in closed vial wastage; and
- Fridges and freezers that provide automatic alerts to health facility staff and, in some cases, to the national maintenance centre – when they are not working properly. This helps ensure that the devices receive immediate attention so the vaccines can be protected.

These capabilities might sound futuristic, but the latest generation of cold chain equipment already achieves this level of performance. Manufacturers are also developing equipment with even more advanced features, which will be available within the next two years.

About this guide

With so many new developments underway, it is critical to use a structured approach to select the right equipment. This guide aims to provide you with clear advice on new CCE technologies to help you make purchasing decisions. It is intended for use in health facilities and lower levels of the cold chain.

In addition, it will help you identify which devices comply with Platform requirements, and choose the cold chain solutions that match the needs of your country's health facilities.

If you have questions or if you would like more information, please contact cceplatform@gavi.org or visit www.gavi.org.

Overview of how to make purchasing decisions

This guide is designed to help you think through which equipment to purchase. It is arranged using the following key to help you complete the decision-making process:



Categorise your health facilities based on CCE needs.

Learn how to divide the health facilities in your country into different groups.



Choose your device types.

For each facility group, learn how to determine what types of devices are appropriate.



Choose your device models.

For each type of device, see what models are available, weigh trade-offs and explore new models expected to become available in the next two years.

Devices covered

This guide covers devices that are used at service delivery points (e.g. health facilities and hospitals) or small cold stores, and which meet or are expected to meet Platform requirements. Larger scale storage (such as absorption refrigerators, solar battery refrigerators and solar direct drive refrigerators with ancillary batteries) are excluded. Specifically, you will find information about the following types of devices:

- Ice-lined refrigerators (ILRs): These vaccine refrigerators run on mains electricity from the national grid or power from a generator. The latest models are designed with longer holdover times to keep vaccines cool during prolonged loss of power (often for more than two days). During normal conditions, many recent models require only eight hours of power per day to keep vaccines within the required temperature range, although limitations on power access may reduce holdover time.
- **On-grid freezers:** These vaccine freezers run on mains electricity from the national grid or power from a generator. They are designed to have better temperature control and reliability than standard domestic freezers.
- Solar direct drive (SDD) refrigerators and freezers: These vaccine refrigerators and freezers run on solar power. In the latest generation, each one of these devices comes with a solar panel that is mounted on either a pole or on the roof of the health facility, and is connected to the device by power cable. Unlike previous solar devices, they do not need batteries and, as a result, they require less maintenance.
- Long-term passive devices: These vaccine storage devices are designed to keep vaccines cold for long periods without any source of power. They do not require solar panels, batteries, electricity, gas or other fuels. They typically have limited vaccine storage capacities (of 10L or less) and keep vaccines cool using a set of icepacks that must be refrozen every three to five weeks.
- **Cold boxes and vaccine carriers:** These insulated containers are used to transport vaccines between facilities or during field immunisation sessions. They use coolant packs (such as cool water-packs or icepacks) that must be re-chilled or refrozen after each use.
- **Temperature monitoring devices:** These devices are used to periodically measure and record temperature readings from cold chain equipment. They display current temperature readings and instances of unacceptable temperature excursions. Some categories of devices also have the ability to transmit SMS-based alarms (in case of excursions) and/or upload temperature data to logistics management information systems (LMIS).

For details about cold chain devices that are not included here, please reference the <u>World Health Organisation</u> (WHO) Performance Quality Safety (PQS) Catalogue.

This guide focuses on equipment selection for service delivery points (e.g. health facilities). Equipment selection for state or district stores involves additional considerations for vaccine transportation and is not addressed here.

Other available tools

While this guide is about choosing the right technology to meet your country's cold chain needs, additional tools are available to help you in other ways.

- WHO Performance Quality Safety (PQS) Catalogue: This catalogue provides detailed specifications on each WHO PQS-approved cold chain device, as well as WHO guidelines for device selection. PQS qualification means that a device has passed a set of performance, quality and safety tests set by WHO.
- **WHO Vaccine Volume Calculator**: This tool determines the total supply chain storage volume needed for the set of vaccines included in a country's vaccination programme.
- WHO Effective Vaccine Management (EVM) Initiative Website: This website provides materials and tools to monitor and assess vaccine supply chains and help countries to improve supply chain performance. It includes background and training resources, EVM Standard Operating Procedures, EVM assessment tools and user guides, and learnings from EVM country assessments. It also contains the Vaccine Management Handbook (below).
- **WHO EVM Initiative Vaccine Management Handbook**: This handbook provides technical advice on immunisation logistics, including the use of cold boxes, vaccine carriers and coolant packs for transport and outreach, and how to monitor temperatures in the supply chain.
- PATH Total Cost of Ownership (TCO) Tool: This tool calculates purchase, delivery, installation and operating costs for a variety of cold chain devices over their expected lifetimes. TCO varies by country due to different labour and energy costs. This guide provides TCO estimates for Nigeria as an example, but the tool can be customised to produce estimates for any country.
- <u>UNICEF Cold Chain Support Package</u>: These documents provide commercial and technical guidance for you to use during procurement of cold chain equipment through the UNICEF Supply Division.
- **UNICEF Supply Catalogue**: In its "Cold Chain Equipment" section, this online catalogue contains many types of devices and includes technical specifications and pricing for each one.
- <u>TechNet-21 Online Resource Library</u>: This section of the TechNet-21 website provides vaccine supply chain technical resources. It includes publications from Project Optimize, a five-year collaboration between WHO and PATH to identify ways to optimise supply chains to meet the demands of an increasingly large and costly portfolio of vaccines.
- <u>"Introducing solar-powered vaccine refrigerator and freezer systems" guide</u>: This document, created by WHO and UNICEF, provides managers in national immunisation programmes with guidance on how to implement solar-powered vaccine refrigerator and freezer systems.



Categorisation Questions

Before making any purchasing decisions, it is necessary to inventory your country's existing cold chain equipment. First, this process will help you sort out which facilities need cold chain equipment, and which do not. Second, this process will also help you assess which makes and models will complement your existing cold chain equipment. Standardising equipment across facilities results in benefits such as simpler training program design and common maintenance networks.

Choosing the correct cold chain solutions for your country's health facilities will require you to assess each facility's characteristics. For purchasing fixed storage devices (i.e. non-portable devices such as refrigerators, freezers and long-term passive devices), the following three questions will help you categorise your health facilities:

- 1. Does the facility have access to reliable electricity?
- 2. Does the facility need to either freeze or chill coolant packs to support outreach?





3. What is the required vaccine storage capacity of the facility?











Accurately categorising your country's health facilities before purchasing any equipment will help you ensure that the diverse needs of facilities are met, and that you can minimise the total cost of ownership (TCO).

Decision Tree Sample

1. DOES THE FACILITY HAVE ACCESS TO RELIABLE ELECTRICITY?

Begin by dividing your country's full set of health facilities in need of cold chain equipment into two segments based on access to electricity via mains or generator.



On-grid

On-grid facilities can access more than eight hours of electricity per day and experience power outages that last fewer than 48 hours.



Off-grid

Off-grid facilities access fewer than eight hours of electricity per day or experience recurring power outages that last more than 48 hours.

Purchasing implications

On-grid facilities should use electricity-powered devices – such as ice-lined refrigerators (ILRs) and on-grid freezers – since they have a lower total cost of ownership than solar or passive devices for the same amount of storage.

Between on-grid facilities, you might see variation in the degree and reliability of electricity access. Your choice of devices should correspond to the number of hours of electricity that a facility can access per day, and the length of electricity outages it experiences.

Number of hours of electricity per day: After a few days of near-continuous power to fully freeze its ice lining, a typical mains- or generator-powered ILR requires at least eight hours of electricity per day to keep its lining frozen and maintain a long holdover time. For facilities that can access more than eight hours of electricity per day, you can choose from a wide variety of ILRs. However, facilities with only four to eight hours of electricity per day will require specially-rated ILRs or may be better served by off-grid solutions. When considering individual models, it will be important to first check how many hours of electricity each model requires. Planning conservatively is key, as actual conditions where a device is used may be more demanding than those where it was tested, and in some locations, devices may need more electricity hours per day than their manufacturer rating indicates.

Length of electricity outages: Choose devices that have a holdover time longer than expected power outages. Current WHO Performance Quality Safety (PQS) requirements require ILRs to have a minimum holdover time of 20 hours. If you expect that a given health facility will experience long power outages, you will need to select an ILR with an appropriately long holdover time.

Another consideration is the ability of on-grid facilities to reliably pay for power. For facilities where reliable payment is not possible, off-grid solutions might be more advisable.

Off-grid facilities should use devices that can generate their own power (such as solar direct drive [SDD] devices) or keep vaccines cold for long periods of time without power (such as long-term passive devices). These devices often cost much more to purchase than on-grid devices, and they have some increased operational costs. For example, SDDs require more routine maintenance, such as regular cleaning of the panels, and long-term passive devices require regular icepack replenishment. However, they also either greatly reduce or completely eliminate electricity costs.

2. DOES THE FACILITY NEED TO EITHER FREEZE OR CHILL COOLANT PACKS TO SUPPORT OUTREACH?

After you narrow down your device categories based on facilities' power access, you can further divide facilities by whether or not they need to produce coolant packs (i.e. freeze icepacks or chill water-packs) for outreach.



Fixed-post immunisation facilities

These facilities rarely rely on outreach and conduct nearly all immunisations on site. As a result, they often do not need to freeze or chill coolant packs on site. For rare occasions when coolant packs are needed, they can be provided by the district store.



Fixed-post immunisation and outreach facilities

These facilities conduct immunisations on site and through multiple outreach sessions per month. They need appropriate on-site capacity to freeze or chill coolant packs for outreach activities.

The choice of coolant pack type depends on the type(s) of vaccines being provided and the temperature in the area where the device is used. WHO currently recommends using water-filled coolant packs. If icepacks are used, they need to be conditioned correctly so vaccines do not freeze. For more information on choice, preparation and use of coolant packs for transport and outreach, please reference WHO Vaccine Management Handbook, Module VMH-E7-02.1: "How to use passive containers and coolant packs for vaccine transport and outreach operations."

Purchasing implications

Fixed-post immunisation facilities do not need to produce coolant packs on site, as they conduct little to no outreach. You need only consider refrigerators or long-term passive devices for storage. If needed, coolant packs for rare outreach sessions can be provided by the district store.

Fixed-post immunisation and outreach facilities conduct more than one outreach session per month. For these facilities, you can assess whether coolant packs need to be either frozen or chilled on site, or whether it might be more cost-effective and programmatically feasible to freeze or chill them off site in other reliable refrigerator or freezer spaces. You can compare the cost of nearby options in the local community or at the district store with the cost of purchasing a dual compartment fridge-freezer or additional fridge or freezer unit for the facility.

It is important to note that coolant packs should not be stored in the same compartment as vaccines. Facilities should use either a dual compartment device, or two separate devices – one for storing vaccines and one for storing coolant packs. The table below will help you factor coolant type into your device choice.

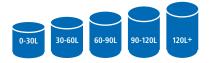
Coolant	Approach	Device for vaccine storage	Device for coolant production	
Iconacks	Two devices	Fridge or long-term passive device	Freezer	
Icepacks -	Dual compartment device	Dual compartme	nt fridge-freezer	
Cool water-packs	Two devices	Fridge or long-term passive device	Fridge	

Devices used to freeze or chill coolant packs should be selected based on the volume and number of packs needed, and their type according to the container used. These devices should be able to completely refreeze or re-chill the required number of packs in the time between sessions.

3. WHAT IS THE REQUIRED VACCINE STORAGE CAPACITY OF THE FACILITY?

The required storage capacity determines the right device size for a facility. The required vaccine storage capacity takes into account three factors:

- Volume of vaccinations per fully immunised child (or per capita);
- Target population size; and
- Vaccine supply frequency and reliability.



In assessing these factors, it is important to plan for not only current needs, but also for future needs over the lifetime of the device. Considerations could include:

- Expected population growth;
- Expected new vaccine introductions, including non-infant immunisations such as HPV vaccines for women of childbearing age (and younger);
- Improved coverage targets;
- Supplemental immunisation activities, such as campaigns

To calculate required vaccine storage capacity, you can use the <u>WHO Vaccine Volume Calculator</u> and the <u>WHO series of modules on immunisation training for Mid-level Managers</u>.

Purchasing implications

If you are making purchases for multiple facilities, it will be useful to group devices into storage capacity bands (0-30L, 30-60L, 60-90L, 90-120L and more than 120L). This might enable you to receive volume discounts from bulk purchases.

On-grid facilities should consider ILRs, dual compartment ILR-freezers and on-grid freezers that have the capacity to store the required amount of vaccines and produce the required amount of coolant. Facilities with very large storage requirements (e.g. state or district stores) might also consider cold rooms and freezer rooms.

Off-grid facilities should consider SDD refrigerators, SDD dual compartment fridge-freezers or SDD freezers. Off-grid facilities requiring less than 5 to 10L of storage – and that have the ability to receive regular ice replenishments – may also consider long-term passive devices.

Long-term passive device implications

Long-term passives are a new device category introduced within the last two years. Due to their limited storage capacity, they are mostly used by small, off-grid facilities. Because they cannot freeze or chill coolant packs, they are not suitable for facilities that perform high levels of outreach unless paired with a separate freezer. Long-term passive devices need a regular and predictable supply of large volumes of icepacks (potentially up to 30 kg for some future devices). Some also require special types of icepacks, which are larger than standard WHO-approved icepacks and shaped differently. Long-term passive devices have two major requirements:

- 1. A nearby delivery hub that can produce enough icepacks per month for each long-term passive device it supports. As each device's icepacks must be replenished every three to five weeks, this process often involves having a spare set of icepacks and using a freezer at the delivery hub. The number of devices that one delivery hub can support will vary. This number should be evaluated based on the existing or planned freezing capacity at the hub, as well as the ice demands of the device(s) being supported.
- 2. A delivery system capable of delivering a monthly shipment of enough icepacks. (The ice must be transported in a box that can keep it frozen.) Motorcycles may not be able to transport large shipments, which can limit ease of access to last-mile facilities.

If either one of these requirements is not met, vaccines could end up being wasted and there could be interruptions in immunisation service at the facilities served by the delivery hub.

Given these restrictions, a solar direct drive (SDD) device should be used instead of a long-term passive device unless a facility meets all of the following conditions:

- An SDD is inappropriate for a particular site or population (e.g. due to insufficient exposure to sunlight);
- On-grid, dependable freezing of icepacks is possible at a nearby supply point;
- Routine delivery systems are capable of stable ice delivery; and
- The required vaccine storage capacity is less than 10L and storage needs are not likely to increase over the next several years.

Other considerations

The answers to the three questions on page 6 are critical for identifying the correct cold chain devices for your health facilities, but there are a few other factors that should be considered before you make a purchase.

- **Ambient temperature range:** It will be important to select a device that is Performance Quality Safety (PQS) tested to operate across the full range of temperatures in the area where the device is being used. As mentioned in the introduction, PQS qualification means a device has passed a set of performance, quality and safety tests set by WHO.
- **Ability to use solar devices:** Solar devices are not suitable for all facilities. Some facilities might be surrounded by buildings or trees that would block solar panels from receiving direct sunlight. Others might not have strong enough sunlight year-round. If you are considering purchasing solar devices, having a site evaluation conducted will help you determine whether a solar device will receive enough power. Solar panels can be mounted on either the roof of the facility or on a separate mounting pole. While a separate mounting pole may mean additional costs, it offers more flexibility for panel placement.

If you find that none of the options in this guide are appropriate for a particular facility, a WHO PQS representative can help you choose the right device. PQS representatives can be contacted via email at pqsinfo@who.int. They can provide support, advice and guidance to help you purchase the most suitable equipment for a given facility's field conditions.

Facility categorisation map

Once you have categorised your country's health facilities by CCE needs, the next section of this guide will assist you in choosing the appropriate device types, and then specific device models. Below, please find some hypothetical examples to help illustrate device selection. These examples are not representative of any specific country, but rather, are intended to help you start assessing the attributes of your facilities.

Small off-grid facility

Less than 8 hours of electricity per day with frequent outages of more than 48 hours



Small target population

Completes all immunisations at the clinic



Potential solution: longterm passive or small solar direct drive refrigerator

Small on-grid facility

More than 8 hours of electricity per day

Several outreach

sessions per month



Potential solution: small dual compartment fridge-freezer ice-lined refrigerator

Potential solution: ice-lined refrigerator

Large on-grid facility

More than 8 hours

Large target

Completes all

immunisations at the clinic

population

of electricity per day

Mid-size off-grid facility

Fewer than 8 hours of electricity per day with frequent outages of more than 48 hours

Large target population

Completes all immunisations at the clinic

Potential solution: solar direct drive refrigerator

Large on-grid facility

More than 8 hours of electricity per day



Several urban outreach sessions per month

Potential solution: large dual compartment fridgefreezer ice-lined refrigerator (ILR) or separate ILR and on-grid freezer

National cold store

Not addressed in this Guide



Used primarily as vaccine storage, rather than point-of-service immunisations

Mid-size off-grid facility

Less than 8 hours of electricity per day with frequent outages of more than 48 hours



Frequent outreach sessions

Potential solution: solar direct drive dual compartment fridgefreezer or separate solar direct drive dual compartment refrigerator and freezer

Worksheet

Categorising your country's health facilities will help you group those with similar traits together. This activity is designed to prepare you to use the next section to choose the right CCE devices and models. By filling out the worksheet below, you can divide your country's full landscape of health facilities into categories and count how many fit into each group.

How many health facilities are in need of new cold chain equipment?



On-grid facilities



Off-grid facilities





Immunisation and outreach facilities



Immunisation facilities



Immunisation and outreach facilities



Immunisation facilities











Cold Chain Equipment (CCE) Optimisation Platform Requirements

Through the Cold Chain Equipment Optimisation Platform, Gavi has committed funds to co-invest with countries to upgrade cold chain equipment. In order for devices to qualify, they must be Performance Quality Safety (PQS) approved by WHO. They must also meet specific requirements for several technology features. This guide focuses on four of the most important features:

- 1. User-independent ("Grade A") freeze protection. WHO PQS defined three grades of freeze protection: A (user-independent), B (requiring one user intervention to prevent freezing), C (requiring more than one user intervention to prevent freezing). The Cold Chain Optimisation Platform subsidises equipment that is Grade A only, i.e., not requiring any user intervention to prevent freezing;
- 2. Extended operating temperature range. This requirement matches what is currently defined by WHO PQS;
- 3. Temperature monitoring and logging. WHO PQS currently requires only Type 1 (the most basic) temperature monitoring devices to be provided with the refrigerator; Type 2 is expected to be provided starting in 2019. However, the Cold Chain Optimisation Platform already subsidises Types 1, 2, and 3; and
- **4. Voltage regulation (for on-grid devices only).** This requirement matches what is currently defined by WHO POS.

1. USER-INDEPENDENT FREEZE PROTECTION

This feature ensures that vaccines are not exposed to freezing temperatures.

User-Independent	Meets Platform requirement	
Grade A	When the device is used within its rated ambient temperature range, the user does not need to perform any actions to protect vaccines from freezing temperatures. For example, the device would not require baskets to protect vaccines from freezing. However, baskets may still be used to sort vaccines in the device.	✓
Grade B	When the device is used within its rated ambient temperature range, the user must perform one action to protect vaccines from freezing temperatures.	X
Grade C	When the device is used within its rated ambient temperature range, the user must perform more than one action to protect vaccines from freezing temperatures.	×

WHO PQS is certifying devices for Grade A freeze protection. Grade A devices that have been certified by WHO PQS are indicated in the tables of currently-available products in this Guide, since these devices are Platform-compliant. Some additional products (indicated by § signs) are shown as being Grade A based on self-reporting by manufacturers. These are not verified as Grade A by WHO PQS, and therefore cannot be procured through Platform funding until PQS verifies their Grade A capabilities. For additional details, please refer to the WHO PQS Catalogue Guidelines, the "Target Product Profile Mains-powered refrigerators WHO/PQS/E003/TPP04" for on-grid refrigerators, and the "Target Product Profile SDD refrigerators WHO/PQS/E003/TPP01" for solar direct drive (SDD) refrigerators.

2. EXTENDED OPERATING TEMPERATURE RANGE

This feature keeps the equipment operating correctly even during large changes in ambient temperature.

Extended operating	Meets Platform requirement	
Moderate	The device operates at a steady 27°C ambient temperature and over a 27°C/10°C day/night cycling temperature range.	X
Temperate	The device operates at a steady 32°C ambient temperature and over a 32°C/15°C day/night cycling temperature range.	X
Hot	The device operates at a steady 43°C ambient temperature and over a 43°C/25°C day/night cycling temperature range.	X
Extended	The device satisfies the requirements for hot zone operation above (43°C), and can also operate at a continuous rated minimum ambient temperature of at most 10°C.	√

For additional details on operating temperature ranges, please reference the <u>WHO PQS Catalogue</u>, as well as the Target Product Profiles for specific devices on the <u>WHO PQS Catalogue Specifications</u> webpage.

3. TEMPERATURE MONITORING AND LOGGING

Once in the field, the refrigerator compartment must be equipped with a temperature recording device that supports the transfer of data to a Logistics Management Information System (LMIS) for analysis. This device can be provided in three ways: 1) as a fully integrated part of the refrigerator, 2) as a separate device, but shipped along with the refrigerator, or 3) as a separate device, shipped separately, but with the price included in the quoted price of the refrigerator.

Temperature moni	toring and logging	Meets Platform requirement
Type 1	The device includes a pre-qualified disposable 30-day temperature logger – with or without an external sensor cord – located in an integrated holder within the vaccine storage compartment. The logger must be positioned for easy reading and located so readings are taken in the minimum temperature zone in the compartment. The logger must meet the requirements of WHO/PQS/E006/TR06.3.	✓
Type 2	The device includes a fully-integrated 30-day temperature logger. The temperature calibration and power source must have a guaranteed life of more than 10 years or have an arrangement for periodic replacement with a pre-calibrated sensor. The temperature logger must meet the requirements of WHO/PQS/E006/TR06.3. If used in a solar device, the temperature monitor should be solar powered.	✓
Type 3	The device has Type 1 or Type 2 temperature monitoring and logging, and can also send SMS alarm messages and potentially integrate with an LMIS platform.	√

4. VOLTAGE REGULATION (FOR ON-GRID DEVICES ONLY)

This feature protects equipment from electrical damage. All voltage regulators must meet WHO PQS certification requirements.

7 Voltage regula	Meets Platform requirement	
Bundled	A separate voltage regulator is included with the purchase of a refrigerator or freezer.	✓
Integrated	A voltage regulator is built into the refrigerator or freezer.	✓

Some voltage regulators have a delay after a power cut before they restart. This delay protects equipment from voltage fluctuations as the power grid re-stabilises. Depending on power quality, this delay can range from six minutes to more than 30 minutes. In choosing a device to purchase, these delays should be factored into the amount of power a device can access each day. Where equipment can be sufficiently protected, a shorter delay might be preferable to ensure access to enough power.

Voltage regulators are used between the electric power outlet and the refrigerator. Regulators are designed to protect AC-powered refrigerators from a range of power-related issues, including voltage or frequency fluctuation (e.g., when a generator is switching on or off) or voltage surges (due to power transmission issues in the grid). This protection from AC power issues can safeguard refrigerator's ECU, compressor, fuses, and other electronic components from damage, and can thereby increase the refrigerator's uptime in the cold chain.

Solar energy harvesting



Solar energy harvesting is not a requirement for Platform compliance, but it is an innovative new feature offered on some current solar direct drive (SDD) devices – and that several other manufacturers are considering incorporating into future models.

Frequently, the panels of an SDD device generate more power than is needed to run a refrigerator unit. Energy harvesting allows health facilities to use excess power from solar panels for other purposes. Depending on voltage specifications, health workers can use devices with energy harvesting to charge cell phones, laptops, radios and battery-powered lanterns, or power devices such as fans and lighting.

Solar energy harvesting is an especially promising capability, as it can evolve an SDD device from a cold chain solution to a potential power hub for other devices at an off-grid clinic.

Overview of future devices

The Platform gives countries the opportunity to upgrade their cold chains with the best and most appropriate equipment available today. Looking ahead, more exciting cold chain technologies are expected to arrive on the market in the next one to two years. These devices and features are designed to address user needs and better protect vaccines.

This guide includes some new CCE devices that are still in the design and testing phases. Information on these devices is included to help inform purchasing planning. However, please bear in mind several limitations. There are also emerging technologies and new device categories that are not mentioned in this Guide because their

development and commercialisation timelines are still uncertain. A new generation of evaporative cooling devices and hand cranked vaccine carriers bypassing the need for ice are in early prototyping phase by several companies. We expect further information about these devices to be included in the 2017 version of this Guide.

- The times to market for these devices are uncertain. Given the variable timelines of development and testing processes, some products may be delayed.
- Device specifications can change during the prototype and testing phases. Devices that are eventually PQS-approved may differ from what is indicated here.
- All information on future devices in this guide has been self-reported by manufacturers who were asked to describe their devices in development (for release in 2016 and beyond). The technical specifications and Platform-compliance of these devices have not been independently validated, nor have the devices been assessed by the WHO Department of Essential Medicines and Health Products Prequalification Team.
- Not all manufacturers opted to provide details on their future products, so this list of future devices does not include every model that will arrive on the market in the next two years.

If you have device-specific questions, you can reach out directly to the manufacturers to receive the latest information.

Device Selection

In the previous section, the worksheet on page 13 helped you divide your health facilities into categories based on electricity access, outreach activities and storage capacity requirements. In the pages that follow, you can identify the current and future devices that meet the needs of each group. You can also compare their features, their compliance with Platform requirements (and their eligibility for co-investment from Gavi) and their total cost of ownership (TCO).

The TCO calculations in this guide assume an effective life of 10 years for all devices. However, a device's actual life will vary based on equipment reliability, local conditions and its maintenance schedule. TCO is expressed through three measures:

- Purchase price, including the cost of both the device and a separate voltage regulator (if not already integrated into the device);
- Delivery and installation costs; and
- Operational expense (Opex), which includes the cost of spare parts, energy, maintenance and repairs for an expected lifetime of ten years, as well as a bundled 30-day temperature logger if required to meet platform requirements.

All TCO figures shown in this guide are calculated using the PATH TCO Tool based on costs representative of a large African country. Appendix A lists the specific assumptions made when calculating from a large African country.

For each entry in the device tables, you will find a link to the model's corresponding page in the <u>UNICEF Supply Catalogue</u>. (For devices that do not currently have a page in the UNICEF Supply Catalogue, you will find a link to the model's page in the <u>WHO PQS Catalogue</u>.) As manufacturers update pricing on a regular basis, please check the UNICEF Supply Catalogue for the latest pricing before making purchasing decisions. If you are purchasing a large number of devices, manufacturers may offer discounts.

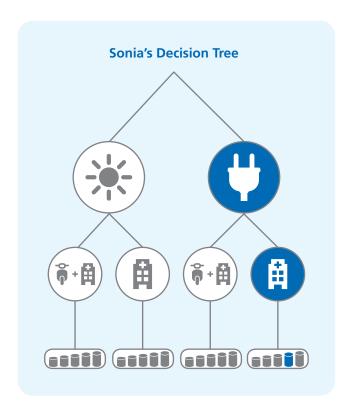
For the information in the device tables, please note the following considerations.

• **Freeze protection:** WHO has recently published a testing protocol for Grade A freeze protection. The device tables indicate which devices have been verified by WHO to meet this protocol. The tables also show which devices are self-reported by manufacturers and expected to comply with the Grade A requirements.

• Device pricing:

- Where available, device pricing is taken from the <u>UNICEF Supply Catalogue</u>. Otherwise, it is taken from the <u>WHO PQS Catalogue</u>.
- All pricing is for a single unit and is current as of the publication date noted on page 1.
- All pricing is in US Dollars (USD) using UN exchange rates as of Jan 2016.
- Prices include the cost of a voltage regulator (where applicable). Prices do not necessarily include the costs of Platform required packaging, operating stickers or photovoltaic cables for solar devices.
- Prices do not include any additional fees incurred when ordering from the <u>UNICEF Supply Catalogue</u>.
- Prices do not reflect the joint investment you may receive from Gavi if you purchase Platformcompliant devices.
- **Delivery costs:** The shipment costs from manufacturer factory to country port have been estimated as a percentage of purchase price. For more expensive devices, this estimate may overstate delivery cost. In-country transport costs are treated as a fixed amount for each device category.
- **Portable devices:** For cold boxes and vaccine carriers, this guide only shows purchase price (rather than TCO), since delivery and operational costs will vary by country and device use.
- **Two-mode devices:** Some single-compartment ice-lined refrigerators (ILRs) can be set to operate as either a fridge or a freezer. These devices are included in the table for current ILRs and have a footnote to indicate that they can also operate as freezers.

Device selection EXAMPLE 1



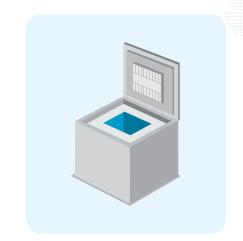
Sonia is a country-level decision maker who has to determine what device will be best for several large, on-grid facilities. These facilities conduct very little research and are not distribution points for vaccines or icepacks.

Decision process: Although these semi-urban facilities consistently have access to more than eight hours of electricity per day, they have occasional power outages of up to 24 hours. A standard (non-ice-lined) refrigerator would be insufficient, but most ice-lined refrigerators can operate with eight hours of electricity per day.

Health workers primarily complete all immunisations at the facility. While they may do one outreach session per month, workers have access to a nearby store's refrigeration systems to obtain chilled waterpacks. If needed, they can also collect frozen icepacks with their monthly vaccine pick-up from the district store for little additional cost.

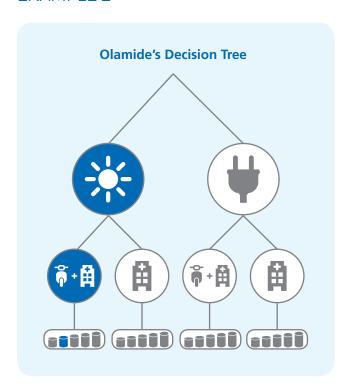
After grouping facilities according to their target population size (and accounting for population growth and new vaccine introductions), using WHO guidance on vaccine volume per fully immunised child and ensuring that vaccines can be reliably delivered on schedule, Sonia determines he needs devices with between 90 and 120L in vaccine storage capacity.

Final Selection: Sonia chooses a Platform-compliant ice-lined refrigerator (ILR) with storage capacity between 90 and 120L for each facility. The ILR is rated to operate with only eight hours of electricity per day. With a holdover in excess of 100 hours, it can easily withstand power outages of three to four days. The ILR also has a much lower total cost of ownership than similarly sized solar devices. Since Platform-compliant devices have Grade A user-independent freeze protection, Sonia knows there is minimal chance of vaccine wastage due to freezing.



Additional considerations: Sonia must purchase and install high-quality voltage regulators with the ILRs to protect them from damage by power surges (if voltage regulators are not already integrated into the devices he chose). Sonia must also purchase and utilise suitable temperature monitoring devices (at least Type 1 or Type 2) in order to: a) immediately know, when looking at the device's display, whether vaccines have been exposed to unacceptable temperatures and b) track the performance of the refrigerator, and to call a technician for maintenance and repair, if required.

Device selection EXAMPLE 2



Olamide is a country-level decision maker who has to determine what devices are best for a group of mid-size, off-grid facilities that complete weekly outreach sessions.

Decision process: These facilities rarely have access to more than a few hours of electricity each week. When they can access electricity, it is inconsistent and unpredictable. Only a solar direct drive (SDD) or long-term passive device will keep vaccines at appropriate temperatures throughout these long periods without power.

Health workers at these facilities engage in weekly outreach activities in their communities. In most cases, there are no places nearby where workers can purchase ice or freeze icepacks, and ice deliveries are too expensive. These facilities require devices with a freezer compartment that can freeze icepacks.

Olamide determines that he needs devices with at least 30L in vaccine storage capacity. This capacity would require four to six long-term passive devices per facility, but only one 30L or larger SDD device. Given the need for freezer capability, the optimal solution would be either dual compartment SDD fridge-freezers or separate SDD refrigerators and SDD freezers.

Final Selection: Olamide decides to purchase a Platform-compliant dual compartment SDD fridge-freezer for each facility. These devices can produce icepacks to support the facility's outreach sessions. Since they are solar powered, they are not affected by the lack of reliable electricity. Olamide also calculates that purchasing a dual compartment SDD fridge-freezer has a lower TCO than purchasing a separate SDD fridge and SDD freezer for each facility.

Additional considerations: To ensure solar compatibility, Olamide must have his sites evaluated for:

- Sufficient sun exposure for the SDD device to function correctly;
- A roof that can support solar panels and any special solar panel mounting equipment required;
- The length of cable required between solar panels and the device; and
- Access to maintenance networks for repairs.

In addition, the freezer compartment of the SDD devices he purchases should be able to store the same size of icepacks (either 0.4L or 0.6L) that the vaccine carriers use for outreach.

Device selection EXAMPLE 3



Michael is a country-level decision maker who has to determine how to address freezing risk when transporting vaccines regionally.

Decision process: A recent temperature monitoring study found that a number of shipments leaving the regional stores exposed vaccines to dangerous freezing conditions. The main contributors were:

- 1. Use of old Styrofoam containers with no insulation between the ice and vaccines; and
- 2. Inconsistent icepack conditioning practices by staff.

To prevent vaccine freezing, Michael initially considers switching to cool water-packs as a lower-cost option. However, per the WHO guidance for mid-level delivery, cool water-packs do not provide enough cold life for heat-sensitive vaccines on long delivery routes. For this reason, Michael decides to look at non-freeze cold boxes to ensure vaccine safety.

He needs to figure out the appropriate volume of the cold boxes, and how to account for different delivery routes. To collect this information, Michael surveys each regional store, and determines both the smallest and largest deliveries they make on a regular basis. On average, the smallest is 25L and the largest is 50L. To address differing route capacity requirements, he chooses two cold boxes so that the smaller and larger capacity routes can be served by one or two boxes respectively.

Final selection: Michael picks a capacity of 30L for use in delivery from regional stores to districts, with each regional store to receive two 30L boxes. However, there are currently no Grade A freeze protected cold boxes available in the market, and the Cold Chain Optimisation Platform only subsidises Grade A cold boxes.

As a result, Michael considers whether to postpone procuring cold boxes until July/August 2016 (when Grade A cold boxes are expected to be available) or to procure existing cold boxes. If Michael chooses the latter option, he knows he must procure the cold boxes with funding from other sources. He therefore decides to wait until July/August 2016, select a Grade A cold box, and utilise Cold Chain Optimisation Platform funding for the procurement.





How to choose between models

If you find more than one model that would meet the needs of a facility, the following factors can help you narrow down your decision:

Individual device characteristics:

- Compliance with Platform requirements, which determines eligibility for Platform funding and reflects a model's higher level of technological capability;
- Holdover time for ILRs based on a facility's power reliability;
 - Devices with extended holdover time are preferable for facilities with less or unreliable electricity
- Autonomy time for SDD devices based on regional climate factors;
 - Devices with extended autonomy time are preferable for facilities in regions with long periods of low sunlight
- Freezer capacity for icepack production;
 - Devices with a freezer compartment are preferable for facilities that need icepacks for outreach or transport
- Total cost of ownership, including delivery and installation costs (as calculated using the PATH TCO tool with your country's inputs); and
- Ease of use, including:
 - Whether devices open at the top or at the front
 As recognised by WHO, front-opening fridges make vaccines
 easier to handle and make earliest-expiry-first-out principles easier
 to implement;
 - Readability of control panels and displays by a standing health worker; and
 - Use of internal storage racks, boxes or drawers to help organise vaccines and separate other medicines that are stored in the device.



Support and standardisation considerations:

- Length and scope of the device's warranty;
- Access to professional in-country installation and maintenance support, including availability of spare parts;
- Quality of after-sales support from the manufacturer, including training for device users; and
- Makes and models of your country's existing cold chain equipment, as standardisation across facilities will enable you to leverage benefits like common maintenance networks.

When choosing between vaccine carriers and cold boxes for transport or outreach, consider the following factors in your decision:

- Compliance with Platform requirements, which determines eligibility for Platform funding and reflects a model's higher level of technological capability;
- Degree of cold life to keep vaccines at safe temperatures for an entire transport or outreach session (including travel to and from the outreach session);
- Storage capacity based on the volume of vaccines that must be transported at any one time for outreach or transport between facilities, and the number of transport or outreach activities that must be supported at any time;
- Durability and construction materials, including whether the device has a soft or hard exterior;
- Portability, factoring in its fully loaded weight and its usability features for transport (e.g. carrying handles, backpack straps or motorbike mounting); and
- Size, type and number of coolant packs required, and their compatibility with other coolant packs used in the country.

On-grid devices



Ice-lined refrigerators (ILRs)



Dual compartment fridge-freezer ILRs



On-grid freezers

Key features

This device has an internal lining of ice, icepacks or cold water-filled compartments

Its internal compressor uses electricity to refreeze or re-cool its lining This device is an ILR with a separate compartment to freeze icepacks This device has a compression-driven system that uses electricity to create ice and freeze icepacks

Outreach capability

Supports high and low levels of outreach

Supports high levels of outreach

Supports high levels of outreach

Vaccine storage capacity



(16-60L)



Number of current Platformcompliant devices

9

1

8

Total cost of ownership

Purchase price: \$570 – 3,280

Delivery and installation:

\$900 - 1,050

Opex: \$2,200 - 3,800

Purchase price: \$820 – 2,450

Delivery and installation: \$900 – 1,000

Opex: \$3,150 - 3,950

Purchase price: \$500 – 2,100

Delivery and installation:

\$800 - 900

Opex: \$2,000 - 4,500

Additional considerations

Most models require 8 hours of electricity per day to re-cool the lining

Some new devices require only 4-6 hours to maintain safe storage temperature. However, more than 4-6 hours of power may be required to build longer holdover times for extended power outages

This device should always be installed with a voltage regulator

Some ILRs with a single compartment can be set to operate as either a fridge or a freezer

Most models require at least 8 hours of electricity per day to re-cool the lining

Some new devices require only 4-6 hours to maintain safe storage temperature. However, more than 4-6 hours of power may be required to build longer holdover times for extended power outages

This device should always be installed with a voltage regulator

This device has an icemaking capability for outreach

Select models can be used to store freezable vaccines (e.g. Oral Polio Vaccine)

It cannot be used to store vaccines that require 2-8°C storage

It should always be installed with a voltage regulator

Chart Legend



Grade A freeze protection—manufacturer-reported



Grade A freeze protection—WHO-verified



Extended operating temperature



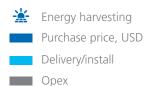
Temperature monitoring/ logging and type (1, 2, 3)



Voltage regulation



Full Platform compliance



Note: In order for the links in the tables to function, please go to **supply.unicef.org** before clicking the links.

CURRENT ICE-LINED REFRIGERATORS

Manufacturer	Model	Vaccine storage capacity, L	Pla	tform con	nplia	nce	Holdover (days)	Purchase price, USD	Total cost of ownership, USD
		Vaccine st	orage	capacity,	120L	+			
Haier	<u>HBC-340</u>	211	業	1 1	7		1.9	955	5,027
B Medical	TCW 3000 AC*	150	*	1	7		2.2	3,281	7,247
Vestfrost	VLS 400A Green Line	145	*	1	7	1	2.3	1,177	4,440
Vestfrost	VLS 400 Green Line	145	業	1 1	7		1.3	967	4,229
Vestfrost	MK 404	135	滐	1	#		1.0	1,014	5,645
Zero (Sure Chill)	ZLF150AC	128	*	1 1	7	1	5.3	3,036	7,461
Vestfrost	VLS 350A Green Line	127	*	1 1	7	1	2.3	1,089	4,216
Vestfrost	VLS 350 Green Line	127	滐	1 1	7		1.3	889	4,017
		Vaccine sto	rage o	apacity, 9	0-12	0L			
Vestfrost	MK 304	105	業	1 1	7		1.1	895	5,577
Godrej (Sure Chill)	GVR100AC	99	*	1	7	✓	12.5	2,050	5,351
Vestfrost	VLS 300A Green Line	98	*	1 1	7	✓	2.3	978	4,113
Vestfrost	VLS 300 Green Line	98	業	1	7		1.0	825	3,961
Zero (Sure Chill)	ZLF100AC	93	*	1	7	1	4.7	2,518	6,895
		Vaccine sto	orage	capacity,	60-90)L			
Haier	<u>HBC-200</u>	90	業	1 1	7		1.3	705	4,244
Vestfrost	MK 204	75	業	1	7		0.8	767	4,642
		Vaccine sto	orage	capacity,	30-60)L	•		
Vestfrost	VLS 200A Green Line*	60	*	1	7	✓	2.3	811	3,965
Vestfrost	VLS 200 Green Line	60	業	1	7		1.0	716	3,870
Haier	<u>HBC-110</u>	53	業	1	#		1.5	605	4,121
Vestfrost	MK 144	48	業	1	7		1.8	671	4,790
Godrej (Sure Chill)	<u>GVR50AC</u>	47	*	1	7	✓	7.6	1,375	4,513
Haier	<u>HBC-70</u>	45	滐	1 1	7		1,1	570	3,667
		Vaccine st	orage	capacity,	0-30	L			
Zero (Sure Chill)	ZLF30AC	27	濼	1 1	7	✓	3.2	1,489	5,201

⁵ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

^{*}TCW 3000 AC and VLS 200 Green Line can also operate as waterpack freezers, but not as dual compartment refrigerator-freezers. Please see WHO PQS catalog for more information on these devices.

FUTURE ICE-LINED REFRIGERATORS

Stage	Manufacturer	Model	Vaccine storage capacity, L	Platform compliance	Holdover (days)
Testing	Dulas	VC 225 ILR	205	* 1 1 7 ✓	3.8
Testing	Aucma	CFD-50 / MetaFridge	50	* 1 1 7 ✓	5.0
Prototype	Godrej (Sure Chill)	GVR 75 AC2G	75	* 1 1 7 ✓	4.2

⁹ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

CURRENT DUAL-COMPARTMENT ICE-LINED FRIDGE-FREEZERS

Manufacturer	Model	Vaccine storage capacity, L	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours	Platform compliance	Holdover (days)	Purchase price, USD	Total cost of ownership, USD
			Vacc	ine storage ca	pacity, 60-90L			
B Medical	TCW 2000AC	60	24 x 0.6	10	* 1 1 7	1.6	2,452	6,604
			Vacc	ine storage ca	pacity, 30-60L			
Vestfrost	MKF 074	16	9 x 0.6	1.6	* 1 1 7	2.2	821	5,658

⁹ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

FUTURE DUAL-COMPARTMENT ICE-LINED FRIDGE-FREEZERS

Stage	Manufacturer	Model	Vaccine storage capacity, L	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours	Platform compliance	loldover (days)
Testing	Vestfrost	VLS 064	50	6 x 0.6	1.8	* 1 1 1 1	0.9

⁹ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

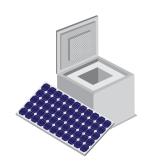
CURRENT ON-GRID FREEZERS

Manufacturer	Model	Max operating temperature	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours	Platform compliance			Holdover (days)	Purchase price, USD	Total cost of ownership, USD	
Haier	<u>HBD 286</u>	43°C	310 x 0.6	16.8	1	1	7	✓	0.2	615	5,880
Vestfrost	MF 314	43°C	256 x 0.6	36.0	1	1	7	✓	0.2	646	5,869
B Medical	TFW 800	43°C	187 x 0.6	7.2	1	1	7	1	n/a	2,101	7,183
Vestfrost	MF 214	43°C	160 x 0.6	7.2	1	1	7	1	0.1	598	5,061
Haier	HBD 116	43°C	136 x 0.6	12.0	1	1	7	1	0.1	530	3,340
Vestfrost	MF 114	43°C	64 x 0.6	7.2	1	1	7	1	0.1	505	4,496
Aucma	<u>DW-</u> 25W147	43°C	144 x 0.6	14.5	1	1	7	✓	0.3	505	5,159
Aucma	<u>DW-</u> 25W300	43°C	46.3kg	38.0	1	1	7	√	2.4	595	5,292





Long-term passive devices



Solar direct drive (SDD) refrigerators



Dual compartment fridge-freezer SDD devices

Key features

This device has a cold life at 43°C of more than 30 days

It requires no active energy source (e.g. sunlight, batteries, electricity or fuel)

It has low maintenance requirements

It has no special installation requirements

This device is powered by solar panel

It requires less maintenance than a solar battery refrigerator

This device is powered by solar panel

It requires less maintenance than a solar battery fridgefreezer

It has dual fridge and freezer compartments to support outreach

Outreach capability

Does not support outreach

Supports high and low levels of outreach

Supports high levels of outreach

Vaccine storage capacity



(5-10L)



(15-170L)



(36-102L)

Number of current Platformcompliant devices

12

Total cost of ownership

Purchase price: \$2,400

Delivery and installation:

Opex: \$800

(excludes ice logistics)

Purchase price: \$2,100 - 6,750

Delivery and installation: \$1,550 - 1,850

Opex: \$1,950 - 2,450

Purchase price:

\$5,900 - 9,550

Delivery and installation: \$1,800 - 2,050

Opex: \$2,000 - 2,500

Additional considerations

This device requires newly frozen icepacks monthly to maintain the appropriate storage temperature

Current devices have a low storage capacity (less than 10L)

This device requires installation by a trained technician

A site evaluation is critical to determine whether solar technology is suitable for a health facility

An alternate approach might be to use pole-mounted solar panels

This device requires installation by a trained technician

A site evaluation is critical to determine whether solar technology is suitable for a health facility

An alternate approach might be to use pole-mounted solar panels

Chart Legend



Grade A freeze protection—manufacturer-reported



Grade A freeze protection—WHO-verified



Extended operating temperature



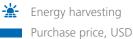
Temperature monitoring/ logging and type (1, 2, 3)



Voltage regulation



Full Platform compliance



Delivery/install

Opex

Note: In order for the links in the tables to function, please go to **supply.unicef.org** before clicking the links.

CURRENT LONG-TERM PASSIVE DEVICES

Manufacturer	Model	Vaccine storage capacity, L	Platform compliance	Cold life at 43°C	Purchase price, USD	Total cost of ownership, USD
Aucma	Arktek-YBC-5	5.40	* 1 1	35	2,393	3,681

Note: The Arktek-YBC-5 requires conditioning of its ice packs before insertion, and is therefore not considered to have Grade A user independent freeze protection. Given the key features of the Arktek and its potential to satisfy specific supply chain needs, the Optimisation Platform will support its purchase on an exceptional basis.

The opex shown here omits the cost of ice logistics. This cost will depend on the cold chain in your country. An estimate can be calculated based on three components:

- The cost of any additional freezer equipment required at the district store;
- The cost of power use to freeze ice; and
- The cost of labour associated with picking up ice from the district store.

FUTURE LONG-TERM PASSIVE DEVICES

Stage	Manufacturer	Model	Vaccine storage capacity, L	Platform compliance	Cold life at 43°C (days)
Testing	Godrej (Sure Chill)	BLF 10 P	8	* 1 1	35

[§] This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

CURRENT SOLAR DIRECT DRIVE REFRIGERATORS

Manufacturer	Model	Vaccine storage capacity, L	Pla	Platform compliance		Autonomy (days)	Purchase price, USD	Total cos ownership		
		Vaccin	e stor	age	capacity,	120L+				
Vestfrost	VLS154 Green Line SDD	170	*	1	1	1	3.1	4,312		8,088
B Medical	<u>TCW 3000SDD</u>	156	濼	1	1		3.6	6,379		10,502
Dulas	VC200SDD	132	*	1	1	✓	3.3	5,021		9,026
Zero (Sure Chill)	ZLF 150DC	128	*	1	1		4.5	5,705		9,515
		Vaccine	stora	age (capacity, 9	0-120	L			
Dulas	VC110 SDD	110	*	1	1	✓	3.8	4,859		9,060
Godrej (Sure Chill)	GVR100DC	99	*	1	1	1	7.3	5,450		9,265
Zero (Sure Chill)	ZLF100DC	93	*	1	1	✓	7.1	5,122		9,240
Vestfrost	VLS094 Green Line SDD	92	*	1	1	✓	3.0	3,421		7,134
		Vaccine	e stor	age	capacity, (60-90	L			
B Medical	TCW 3043	89	*	1	1	1	4.9	6,742		10,878
Dulas	VC88 SDD	88	濼	1	1	1	3.8	4,781		8,976
		Vaccine	e stor	age	capacity,	30-60	L			
Vestfrost	VLS 054 Green Line SDD	56	*	1	1	✓	3.0	2,937		6,617
SunDanzer	BFRV-55 SDD	55	*	1	1	✓	3.5	3,035		6,810
Godrej (Sure Chill)	<u>GVR50DC</u>	47	*	1	1	1	5.6	4,070		7,827
		Vaccin	e sto	rage	capacity,	0-30L				
Zero (Sure Chill)	ZLF30DC SDD	27	濼	1	1		3.2	2,064		6,071
SunDanzer	BFRV-15 SDD	15	濼	1	Î	1	4.2	2,290		5,836

⁵ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

FUTURE SOLAR DIRECT DRIVE REFRIGERATORS

Stage	Manufacturer	Model	Vaccine storage capacity, L	Pla	tfor	m compli	ance	Autonomy (days)
Testing	Haier	HTC-110	60	*	1	1	√	4.1
Testing	Vestfrost	VLS 024	25	*	1	1	✓	3.5
Testing	Haier	HTC-40	22.5	*	1	1	✓	5.0
Prototype	Dulas	VC 50	50	*	1	1	1	4.2
Prototype	Dulas	VC 30	30	*	1	1	✓	4.2

⁵ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

CURRENT DUAL-COMPARTMENT SOLAR DIRECT DRIVE FRIDGE-FREEZERS

Manufacturer	Model	Vaccine storage capacity, L	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours		Platform compliance			Autonomy (days)	Purchase price, USD	Total cost of ownership, USD
			Va	ccine storage cap	acity	90	-120L				
Dulas	<u>VC150FF</u>	102	20 x 0.6	2.04	*	1	1	1	3.2	7,212	11,603
Haier	HTCD-160	100	18 x 0.6	2.08	*	1	1	1	5.1	6,500	10,350
B Medical	<u>TCW_</u> 2000SDD	99	24 x 0.6	2.40	*	1	1		3.6	9,226	13,559
			V	accine storage cap	pacity	, 6C	-90L				
B Medical	<u>TCW</u> 2043SDD	70	16 x 0.6	2.50	**	1	1	1	3.1	9,544	13,730
			V	accine storage cap	pacity	, 30	-60L				
B Medical	TCW 40SDD	36	8 x 0.6	1.80	*	1	1	1	3.4	5,907	9,927

⁹ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

FUTURE DUAL-COMPARTMENT SOLAR DIRECT DRIVE FRIDGE-FREEZERS

Stage	Manufacturer	Model	Vaccine storage capacity, L	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours	Platform compliance		Energy harvesting	Autonomy (days)	
Testing	Haier	HTCD-90	160	20 x 0.6	2.4	1	1	√	-*-	4.1
Testing	Dulas	VC 60FF	57	20 x 0.6	2.4	1	1	✓	*	3.8
Prototype	Aucma	Arktek TBC-10S	10	4 x 0.4	0.21	1	1	✓	*	7.0

FUTURE SOLAR DIRECT DRIVE FREEZERS

Stage	Manufacturer	Model	Vaccine storage capacity, L	Waterpack storage capacity, L	Waterpack freezing capacity, kg/24 hours	Platform compliance		Energy harvesting	Autonomy (days)
Testing	SunDanzer	DDF 50	n/a	30 x 0.6	1.8	1 1	1	*	n/a
Testing	Haier	HTD-60H	n/a	16 x 0.6	3	1 1		<u>*</u>	n/a
Prototype	Dulas	VC 30F	n/a	30 x 0.6*	TBD	1 1	1	*	n/a

^{*}Estimated





Carriers



Cold boxes

Key features

This device is an insulated container used to transport and store vaccines for immunisation sessions

This device is a larger, portable, insulated container

It is used for transportation between sites, storage during immunisation sessions and multi-day outreach activities

Outreach capability

Supports high levels of outreach

Supports high levels of outreach

Vaccine storage capacity



(1-4L)



(6-57L)

Number of current Platformcompliant devices





Total cost of ownership

Purchase price: \$8 - 300

Purchase price: \$87 – 680

Additional considerations

Before purchasing, consider the maximum acceptable fully loaded weight, durability, shape/ size and how long vaccines stay cold/cool when used with icepacks or chilled waterpacks

Coolant pack standardisation should be considered if multiple carriers are used

Before purchasing, consider the maximum acceptable fully loaded weight, durability, shape/size and how long vaccines stay cold/cool when used with icepacks or chilled waterpacks

Coolant pack standardisation should be considered if multiple carriers are used

^{*}Until Grade A freeze protected cold boxes and vaccine carriers are available in the market, countries may procure existing products on a transitional basis. However, funding from the Cold Chain Optimisation Platform cannot be utilised to procure these non-Grade A cold boxes and carriers.

Chart Legend



Grade A freeze protection—manufacturer-reported



Grade A freeze protection—WHO-verified



Extended operating temperature



Temperature monitoring/ logging and type (1, 2, 3)



Voltage regulation



Full Platform compliance



Opex

Note: In order for the links in the tables to function, please go to **supply.unicef.org** before clicking the links.

CURRENT VACCINE CARRIERS

Manufacturer	Model	Vaccine storage capacity, L	Fully loaded weight, kg	Platform compliance	Cold life at 43°C (days)	Cool life at 43°C (days)	Purchase price, USD
B Medical	RCW 4	3.6	7.3	※ 1	1.26	0.28	239
Cold & co.	COLDPACK 7 lt D	3.2	7.8	※ 1	1.30	n/a	50
Nilkamal Limited	BCVC 46	2.7	6.4	※ 1	1.93	0.57	16
Colombo Smart Plastic	Gio Style VC2.6L	2.7	6.5	* 1	1.73	0.51	26
Blowkings	BK-VC2.6CF	2.6	4.5	* 1	1.79	0.29	16
AOV International	<u>AVC-46</u>	2.5	6.4	* 1	2.09	0.41	15
SAVSU Technologies	PHD-9	2.1	5.6	* 1	1.85	0.48	295
Xinxiang Dengke	DENCO LCX-6L	1.8	4.7	* 1	1.64	0.45	12
Blowkings	BK-VC1.7CF	1.7	4.0	* 1	1.58	0.25	12
Nilkamal Limited	BCVC 43	1.5	4.9	* 1	1.71	0.40	13
Nilkamal Limited	BCVC 44A	1.4	4.9	* 1	1.65	0.36	12
Xinxiang Dengke	DENCO LCX-3.6L	1.4	3.2	* 1	1.64	0.34	13
Apex International	AIVC-44	1.4	4.3	* 1	1.63	0.26	13
AOV International	<u>AVC 44</u>	1.4	4.4	* 1	1.67	0.33	12
Blowkings	VDC-24-CF	1.0	2.2	* 1	0.83	0.13	9
Nilkamal Limited	BBVC-23	0.9	2.4	* 1	0.74	0.19	9
Apex International	AIDVC-24	0.8	2.3	* 1	0.90	0.19	9
AOV International	ADVC-24	0.8	2.2	* 1	0.84	0.19	8

Note: This table uses UN exchange rates as of 8/2015. The purchase price represents the listed PQS bulk price (200+ units).

FUTURE VACCINE CARRIERS

The Portevap is a new technology of vaccine carrier currently in development by Global Good. The Portevap product (PE1000) is designed to be Grade A freeze protected, with lengthy cold life, and aimed at eliminating the need for ice packs in outreach. The Portevap is intended for use in outreach to hard-to-reach regions, in eradication campaigns, or in outreach from off-grid health facilities.

The device contains a rechargeable thermal battery that can be charged through either mains power or solar power. Once fully charged, the thermal battery can maintain a constant 5°C vaccine temperature for at least 5 days at a constant ambient temperature of 43°C, according to testing by Global Good. The thermal battery can be turned on or off, thereby enabling its charge to be conserved for use only when required.

The device is currently undergoing lab testing, design, and field testing, with a small field test in Nigeria confirming the device's lengthy cold life capabilities. In the upcoming months, additional work by Global Good will finalise the price of the product as well as plans for PQS qualification.

Manufacturer	Model	Vaccine storage capacity, L	Fully loaded weight, kg	Platform complia	Platform compliance		Cool life at 43°C (days)	Purchase price, USD
Global Good	PE1000	2	8	* 1	1	5	n/a	n/a at present

⁵ This Grade A freeze protection rating is self reported by the manufacturer. The product has not yet been verified by WHO PQS as being Grade A freeze protected. This product will not be procured with Platform funding until certified as Grade A by WHO PQS.

CURRENT COLD BOXES

Manufacturer	Model	Vaccine storage capacity, L	Fully loaded weight, kg	Platform compliance	Cold life at 43°C (days)	Cool life at 43°C (days)	Purchase price, USD
Nilkamal Limited	RCB 444 L	57	38	業 ▮	5.42	1.12	130
EBARA Co. Ltd.	<u>EBT-30</u>	30	15	※ ▮	2.52	0.77	400
Blowkings	CB-20-CF	24	50	業 ▮	5.75	1.29	160
AOV International	ACB 316 L	24	48	業 ▮	6.08	1.44	122
AOV International	ACB 246 LS	23	35	業 ▮	3.90	0.86	92
Apex International	AICB 503 L	23	48	* ▮	5.34	1.30	135
AOV International	ACB 503 L	23	46	* ▮	5.27	1.17	122
Apex International	AICB 444 L	22	49	* 1	5.83	1.04	135
Nilkamal Limited	RCB 264 SL	22	28	* 1	4.42	1.25	99
AOV International	<u>ACB 444 L</u>	22	46	業 ▮	6.13	1.28	122
AOV International	ACB 324 SS	21	34	* 1	3.35	0.78	92
B Medical	RCW 25	21	39	※ ▮	5.61	1.43	683
Nilkamal Limited	RCB 444L-A	20	50	業 ▮	6.35	2.14	132
Nilkamal Limited	RCB 246 LS	18	35	業 ▮	3.06	1.09	100
Nilkamal Limited	RCB 324 SS	15	32	業 ▮	2.23	0.88	100
Blowkings	<u>CB-12-CF</u>	14	45	業 ▮	6.50	1.38	110
AOV International	ACB 264 SL	12	25	業 ▮	5.51	1.24	87
Blowkings	<u>CB-55-CF</u>	9.7	23	業 ▮	3.71	0.83	100
B Medical	RCW 12	9.2	23	* 1	4.79	1.10	538
Apex International	<u>AICB 243 S</u>	8.3	22	* 1	3.50	0.71	139
B Medical	RCW 8	7.1	16	* 1	2.41	0.50	280
Nilkamal Limited	RCB 264 SS	6.3	29	業 ▮	3.32	0.86	97

Note: This table uses UN exchange rates as of 8/2015. The purchase price represents the listed PQS bulk price (200+ units).

Temperature Monitoring Solutions

Temperature monitoring devices (TMDs) are used to monitor the performance of CCE in maintaining the safe 2-8°C range. Modern TMDs are designed to provide both a view of the current storage temperature, as well as a digital record of the temperatures – and high-risk events – over time.

In order to maintain vaccine quality, it is essential to monitor the temperature of vaccines throughout the supply chain. When done properly, this monitoring achieves the following goals:

- Identifies malfunctioning cold chain equipment, reducing risk to vaccines;
- Alerts health workers and supervisors to high-risk temperature exposures, so that corrective vaccine management and CCE maintenance actions can be taken. (e.g. testing/disposal of vaccines, repair of CCE)

Having an appropriate temperature monitoring device (TMD) is critical for achieving these goals. For health facilities and subnational stores, WHO recommends the 30-Day Temperature Recorders (30-DTRs)¹. These devices display a) the current temperature, and b) a rolling 30-day history of all high-risk freezing and heat events². This is a significant improvement over stem thermometers, which fail to alert health workers to events occurring between routine monitoring checks.

30-DTRs also facilitate more efficient reporting on CCE performance, using the monthly count of alarms. Some newer models also allow records to be downloaded and printed, by connecting the device to a PC via USB.

Note: 30-DTRs are battery powered, with devices lasting between two to five years (depending on model). As such, it is important to anticipate future re-procurement within broader cold chain planning.

30-DTRs listed on the WHO PQS catalogue:

Manufacturer	Model	Data download and interface	Battery shelf life (months)	Activated life (months)	Unit purchase price, USD
Berlinger	Fridge-tag	No	12	24	25.0
Berlinger	Fridge-tag 2	Yes (USB)	12 (inactivated) + 24 (activated)	42	44.0
Logtag Recorders	VaxTag	Yes (LogTag Interface Cradle + USB)	n/a	24-36	40.8
ELPRO-BUCHS AG	LIBERO Ti1	Yes (USB)	14 (no activation)	13 (400 days)	150.0

Note: All devices have a visual alarm and non-replaceable batteries. Purchase price represents the listed PQS price for an order quantity of 20+ units. Unit purchase price for LIBERO Ti1 is for an order quantity of 10+ units.

¹ Refer to the WHO Vaccine Management Handbook Module on How to Monitor Temperatures in the Vaccine Supply Chain (Module VMH-E2-01.1) for detailed guidance.

² A high risk freezing event is defined as >60 minutes below -0.5°C. A high risk heat event is defined as >10h above 8°C]

CONCLUSION

Gavi's Cold Chain Optimisation Platform is designed to support countries with rehabilitating and expanding the cold chain by appropriately selecting, procuring, and deploying the optimised products presented in this brochure. Countries could benefit in three ways from these optimised products. First, the products would enable the cold chain to reach more facilities, including facilities that were previously hard-to-reach. Second, the products would offer improved temperature control to vaccines, including the elimination of the risk of freezing. Third, the products would remain functional in challenging operating conditions for longer periods of time; additionally, recorded temperature data would offer the potential to inform preventative maintenance and repair systems.

Together, these three benefits could enable countries to improve vaccine availability, increase vaccine safety, and maintain vaccine potency. As a result, more children in more locations could receive effective vaccines, thereby improving country immunisation coverage. This, along with the lower operating costs of many of the optimised products, could support countries with implementing more cost-effective and high-impact immunisation systems.

ACRONYM KEY

CCE

Cold Chain Equipment

EVM

Effective Vaccine Management

Gavi

Gavi, the Vaccine Alliance

ILR

Ice-Lined Refrigerator

PCM

Phase Change Material

PQS

Performance Quality Safety

SDD

Solar Direct Drive

TCO

Total Cost of Ownership

UN

United Nations

UNICEF

United Nations Children's Rights & Emergency Relief

WHO

World Health Organisation

DEFINITIONS

Autonomy: The autonomy of a solar refrigerator measures the ability of the equipment to store vaccine during periods of heavy cloud. It is defined as the maximum number of days during which the refrigerator can maintain a full vaccine load at a temperature between 2°C and 8°C when the photovoltaic panels are not generating electricity.

Holdover time: The time in hours during which all points in the vaccine compartment of a vaccine refrigerator remain below 10°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected. For vaccine freezers, the holdover time is the time in hours during which the vaccine compartment remains below -5°C.

Cold life and cool life for cold boxes and vaccine carriers: Cold life applies when fully frozen water-packs are used as the coolant. These will continue to be used for transporting Oral Polio Vaccine and single antigen freezedried vaccines. Cool life applies when cool water-packs are used.

- **Cold life with frozen water-packs:** Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches 10°C, at a constant ambient temperature of 43°C.
- Cool life with cool water-packs at 5°C: Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches 20°C, at a constant ambient temperature of 43°C.

APPENDIX A

For total cost of ownership (TCO) figures, this guide uses the PATH Total Cost of Ownership (TCO) tool with the key assumptions below. As these assumptions will vary by cold chain system, the tool should be used with assumptions for your cold chain so you can estimate the most accurate TCO for your purchase. All costs are in US Dollars (USD) using UN exchange rates as of Jan 2016.

Country inputs:

• Cost of technician labour: \$5.63 per hour

• Cost of electricity: \$0.09 per kilowatt hour (kWh)

Purchase price assumptions:

- Devices: All device pricing is the price for a single unit. Where available, device pricing is taken from
 the <u>UNICEF Supply Catalogue</u>. Otherwise, it is taken from the <u>WHO Performance Quality Safety</u>
 (<u>PQS</u>) <u>Catalogue</u>. The price does not include UNICEF's handling fee of 8% for least developed countries
 or 8.5% for non-least developed countries.
- Accessories: The purchase price includes the cost of a voltage regulator when one must be bundled with the device to meet Platform requirements.

Delivery and installation assumptions:

Delivery and installation assumptions	ILR	On-grid freezer	Long-term passive device	SDD device
Cost of freight from manufacturer to country port	7% of unit, spare part and installation kit cost	7% of unit, spare part and installation kit cost	7% of unit, spare part and installation kit cost	7% of unit, spare part and installation kit cost
Cost of in-country freight	\$550	\$550	\$150	\$550
Amount of installation labour (at assumed rate of \$150 per day per technician)	1 technician for 1 day	1 technician for 1 day	1 technician for 1 day	2 technician for 2 days

Opex assumptions:

- Spare parts: The set of parts is per UNICEF Catalogue recommendations per unit. (Where spare parts are for 10 units, the cost is divided by 10.) Where available, parts pricing is taken from the UNICEF Supply Catalogue. Otherwise, it is taken from the WHO PQS Catalogue.
- Temperature monitor: The opex cost includes the cost of one 30-day temperature logger if the device does not already have 30-day logging capability.

Maintenance assumptions	ILR	On-grid freezer	Long-term passive device	SDD device
Routine maintenance	1 hour per month for defrosting/cleaning; 1 hour onsite preventive maintenance visit annually	1 hour per month for defrosting/cleaning; 1 hour onsite preventive maintenance visit annually	1/4 hour per month for cleaning; 1 hour onsite preventive maintenance visit annually	1 hour per month for defrosting/cleaning; 2 hour onsite preventive maintenance visit annually
Repair maintenance	4 hours in workshop every 4 years	4 hours in workshop every 4 years	n/a	4 hours in workshop every 4 years

The Cold Chain Equipment Optimisation Platform has been developed through the collaboration of the following Vaccine Alliance partners:















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